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10/533,206	04/28/2005	Michael L. King	PU4891USW	9099
23347 7590 04/18/2008 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/533,206

Applicant(s)

KING, MICHAEL L.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01.09.2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date 01.11.2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on January 9th, 2008 have been fully considered but they are not persuasive. The applicant argues that positions 13 and 14 of Bacon are not "tapered sections". The examiner disagrees with the applicant's arguments. Page 8 lines 29-31 of the reference clearly states that the section 17.1 has thinner sections implying that the diameter has changed which inherently defines a tapered section.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 4-10, 13, 14, 21-23, 25-27, 29-40, 42, 43, 47-49, 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon et al. (WO 98/41254).

4. As to claim 2, Bacon teaches an aerosol dispensing device that comprises a container 2 (see abstract) having a pharmaceutical formulation comprising at least one medicament present therein; a metering assembly 5 and 6 (see abstract) in communication with the container (see figures 1 and 2); a tubular nozzle 11, 13 and 14 (see figure 2) having an inlet configured in size to communicate with the metering assembly (see figure 2), and an outlet for directing the medicament to a patient (see figure 2), wherein the tubular nozzle has at least one curved portion; wherein the tubular nozzle has a defined length and a longitudinal axis that is curvilinear

throughout the defined length of the tubular nozzle (see figure 2), the tubular nozzle having a radius of curvature of at least 2.5 times the inner diameter of the tubular nozzle present within the curved portion (**the tubular nozzle 11, 13 and 14 of the Bacon is inherently capable of having a radius of curvature of at least 2.5 times the inner diameter of the tubular nozzle present within the curved portion**), wherein the tubular nozzle includes at least one tapered section (see figure 2; **the section left of reference character 14 is defined as tapered**).

5. **As to claims 4 and 29**, Bacon teaches an apparatus wherein the at least one tapered section is positioned at a proximal end of the tubular nozzle (see figure 2; **the section left of reference character 14 is defined as tapered**).

6. **As to claims 5 and 30**, Bacon teaches an apparatus wherein the at least one tapered section is positioned at a distal end of the tubular nozzle (see figure 2; **the section right of reference character 13 is defined as tapered**).

7. **As to claims 6 and 31**, Bacon teaches an apparatus wherein the at least one tapered section decreases in the direction of the distal end of the tubular nozzle (see figure 2; **the section left of reference character 14 is defined as tapered**).

8. **As to claims 7 and 32**, Bacon teaches an apparatus wherein the at least one tapered section increases in the direction of the distal end (see figure 2).

9. **As to claims 8 and 33**, Bacon teaches an apparatus wherein the tubular nozzle includes at least one linear portion (see figure 2).

10. **As to claims 9 and 34**, Bacon teaches an apparatus wherein the tubular nozzle includes a plurality of linear portions located at a distal end of the tubular nozzle and a proximal end of the tubular nozzle (see figures 1 and 2).

11. **As to claims 10 and 35**, Bacon teaches an apparatus wherein the tubular nozzle includes at least one throat (see figure 2).
12. **As to claims 13 and 47**, Bacon teaches an apparatus wherein the tubular nozzle is constructed from a polymeric material (see page 8 lines 5-15).
13. **As to claims 14 and 48**, Bacon teaches an apparatus wherein the polymeric material is selected from the group consisting of polyethylene (PE), polypropylene (PP), polymethylmethacrylate (PMMA), polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl fluoride (PVF), polyvinylidene fluoride (PVDF), polychlorotrifluoroethylene (PCTFE), polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), perfluoroalkoxy (PFA), polyamide (PA), polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyetherimide (PEI), polyamideimide (PAI), polyimide (PI), polysulfone (PS), polyaralsulfone (PAS), polyethersulfone (PES), polyphenylene sulfide (PPS), polyetheretherketone (PEEK), polydimethylsiloxane (PDMS) and polycarbonate (PC), combinations thereof and blend thereof (see page 8 lines 5-15).
14. **As to claims 21 and 56**, Bacon teaches an apparatus wherein the outlet of the tubular nozzle is oriented substantially horizontal (see figure 2).
15. **As to claim 22**, Bacon teaches an apparatus wherein the system is present as an oral inhaler (see page 8 lines 10-15).
16. **As to claim 23**, Bacon teaches an apparatus wherein the system is present as an intranasal inhaler (see page 8 lines 10-20).
17. **As to claim 25**, Bacon teaches an apparatus wherein the system is present as an oral inhaler, and wherein the container is present as a canister, the pharmaceutical formulation is

present as a pharmaceutical aerosol formulation (**see abstract**) comprising the at least one medicament and at least one propellant, the metering assembly is present as a metering valve assembly including a valve stem wherein a passage for dispensing the at least one medicament is positioned in the valve stem; and wherein the inlet of the tubular nozzle is configured in size to communicate with the dispensing passage (**see figures 1 and 2**).

18. **As to claim 26**, Bacon teaches an apparatus wherein the inlet of the tubular nozzle is aligned with the dispensing passage (**see figures 1 and 2**).

19. **As to claim 36**, Bacon teaches an apparatus wherein the inhaler further comprises a means of actuation containing the canister and wherein the means of actuation assists in delivering medicament to a patient (**see page 8**).

20. **As to claim 37**, Bacon teaches an apparatus that further comprises a mouthpiece **19** having an outlet, wherein a portion of the tubular nozzle containing the tubular nozzle outlet is positioned in the mouthpiece (**see figures 1 and 2; page 8 lines 10-20**).

21. **As to claim 38**, Bacon teaches an apparatus wherein the outlet of the tubular nozzle has an exit orifice **16**, and wherein the exit orifice is substantially even with the outlet of the mouthpiece (**see figures 1 and 2**).

22. **As to claim 39**, Bacon teaches an apparatus wherein the exit orifice of the tubular nozzle is recessed from the outlet of the mouthpiece (**see figures 1 and 2**).

23. **As to claim 40**, Bacon teaches an apparatus wherein the portion of the tubular nozzle containing the tubular nozzle outlet is coaxial with the central axis of the mouthpiece (**see figures 1 and 2**).

24. **As to claim 42**, Bacon teaches an apparatus that further comprises a connector 12 that receives a proximal end of the tubular nozzle, and wherein the connector engages the valve stem (see figures 1 and 2).
25. **As to claim 43**, Bacon teaches an apparatus wherein the tubular nozzle and the connector are constructed from the same material (see page 8).
26. **As to claim 49**, Bacon teaches an apparatus wherein the diameter of the inlet of the tubular nozzle is similar to the diameter of the dispensing passage (see figures 1 and 2).
27. **As to claim 58**, Bacon teaches a method step of providing a system as defined by claim 1 and activating the system to deliver the at least one medicament to the patient (see page 8).

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

30. Claims **3, 11, 12, 24, 28, 41, 44-46 and 57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon et al. (WO 98/41254).

31. **As to claims 3, 28 and 41**, Bacon substantially discloses the claimed invention; see rejection of claims 1, 2, 25, 27 and 37 above, but does not disclose a tubular nozzle having a tapered section that has an angle less than about 45 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a tapered section that has an angle less than 45 degrees in order to provide better connection with the metering assembly or the outlet, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

32. **As to claims 11, 12 and 44-46**, Bacon substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a tubular nozzle that is from a metallic material wherein the metallic material comprises a metal selected from the group consisting of stainless steel, gold, nickel, brass, aluminum, titanium, tantalum, iron, and combination thereof. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bacon's invention by providing a tubular nozzle that is from a metallic material wherein the metallic material comprises a metal selected from the group consisting of stainless steel, gold, nickel, brass, aluminum, titanium, tantalum, iron, and combination thereof in order to improve the delivery process, since it has been held to be within the general skill a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

33. **As to claims 24 and 57**, Bacon substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose at least one additional tubular nozzle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bacon's invention by providing an additional tubular nozzle in order to provide a backup in case the other tubular nozzle is damaged, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

34. Claims **15-20, 50-55 and 59-64** rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon et al. (WO 98/41254) in view of Rand et al. (US 6,360,739).

35. **As to claims 15, 20, 50-55 and 59-64**, Bacon substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a medicament selected from the group consisting of analgesics, anginal preparations, antiallergics, antinfectives, antihistamines, anti-inflammatories, antitussives, diuretics, hormones, therapeutic proteins, peptides, medicament for treating erectile dysfunction, fluticasone, beclomethasone, salmeterol, albuterol, ipratropium, salts thereof, esters thereof, solvates thereof, albuterol sulfate, salmeterol xinafoate, fluticasone propionate and combination thereof. Rand discloses an apparatus that doe comprise a medicament selected from the group consisting of analgesics, anginal preparations, antiallergics, antinfectives, antihistamines, anti-inflammatories, antitussives, diuretics, hormones, therapeutic proteins, peptides, medicament for treating erectile dysfunction, fluticasone, beclomethasone, salmeterol, albuterol, ipratropium, salts thereof, esters thereof, solvates thereof, albuterol sulfate, salmeterol xinafoate, fluticasone propionate and combination thereof (see column 9). Therefore,

it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bacon's invention providing a medicament selected from the group consisting of analgesics, anginal preparations, antiallergics, antinfectives, antihistamines, anti-inflammatories, antitussives, diuretics, hormones, therapeutic proteins, peptides, medicament for treating erectile dysfunction, fluticasone, beclomethasone, salmeterol, albuterol, ipratropium, salts thereof, esters thereof, solvates thereof, albuterol sulfate, salmeterol xinafoate, fluticasone propionate and combination thereof as taught by rand in order to provide the proper treatment to the proper patient.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
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